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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,569	12/05/2003	Michael Tovey	2121-0179P	8091

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EXAMINER	
MCGILLEM, LAURA L	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 09/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/727,569	TOVEY, MICHAEL	
	Examiner	Art Unit	
	Laura McGillem	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 October 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-95* is/are pending in the application.

4a) Of the above claim(s) *1-45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *46-95* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 46-59, drawn to a method for expressing in a eukaryotic cell, a polypeptide capable of interacting with a designated nucleotide sequence and capable of acting as a positive transcription factor, comprising expressing a polynucleotide in said eukaryotic cell, classified in class 435, subclass 71.1, for example.

II. Claims 60-63, 72-76 and 78-86, drawn to a polynucleotide, a recombinant vector, a recombinant eukaryotic cell comprising the polynucleotide sequence and a composition comprising a polynucleotide or a recombinant cell, classified in class 514, subclass 44, for example.

III. Claims 64-71, 77 and 86, drawn to a recombinant polypeptide, a recombinant eukaryotic cell and composition comprising a recombinant polypeptide, classified in class 530, subclass 300, for example.

IV. Claims 87-89, drawn to a method of treating a subject with a composition, classified in class 514, subclass 44, for example.

V. Claims 90-92, drawn to a method for the *in vitro* detection of a deficient gene, classified in class 435, subclass 6, for example.

VI. Claims 93-95, drawn to a method for screening compounds for activity of regulating transcriptional activity, classified in class 435, subclass 6, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are patentably distinct because they are structurally, biochemically and functionally different. The polypeptide of Group III is not required for the use of the polynucleotide of Group II, and the polynucleotide of Group II is not required for the use of the polypeptide of Group II.

Inventions I and IV-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are patentably distinct methods comprised of different steps which result in distinct outcomes. The method of Group I is distinguished from the methods of Groups IV-VI, because it is a method for expressing a polypeptide in a cell, while the method of Group IV is a method of treating a subject with a composition and the method of Group V is a method for *in vitro* detection of a deficient gene and the method of Group VI is a method for screening compounds for transcriptional regulation activity. The outcome of the method of Group I is a polypeptide expressed in a cell, which is distinct from the outcome of the method of Group IV, which is a treated subject, distinct from the outcome of the method of Group V, which is

detection of a deficient gene, and distinct from the outcome of the method of Group VI, which is detection of a DNA-compound complex.

The method of Group IV is distinguished from the methods of Groups I, V-VI, because it is a method of treating a subject with a composition, while the method of Group I is a method for expressing a polypeptide in a cell, and the method of Group V is a method for *in vitro* detection of a deficient gene and the method of Group VI is a method for screening compounds for transcriptional regulation activity. The outcome of the method of Group IV is a treated subject, which is distinct from the outcome of the method of Group I, which is a polypeptide expressed in a cell, distinct from the outcome of the method of Group V, which is detection of a deficient gene, and distinct from the outcome of the method of Group VI, which is detection of a DNA-compound complex.

The method of Group V is distinguished from the methods of Groups I, IV and VI, because it is a method for *in vitro* detection of a deficient gene, while the method of Group IV is a method of treating a subject with a composition and the method of Group I is a method for *in vitro* detection of a deficient gene and the method of Group VI is a method for screening compounds for transcriptional regulation activity. The outcome of the method of Group V is detection of a deficient gene, which is distinct from the outcome of the method of Group I, which is a polypeptide expressed in a cell, distinct from the outcome of the method of Group IV, which is a treated subject, and distinct from the outcome of the method of Group VI, which is detection of a DNA-compound complex.

The method of Group VI is distinguished from the methods of Groups I and IV-V, because it is a method for screening compounds for transcriptional regulation activity, while the method of Group IV is a method of treating a subject with a composition and the method of Group V is a method for *in vitro* detection of a deficient gene and the method of Group I is a method for expressing a polypeptide in a cell. The outcome of the method of Group VI is detection of a DNA-compound complex, which is distinct from the outcome of the method of Group IV, which is a treated subject, distinct from the outcome of the method of Group V, which is detection of a deficient gene, and distinct from the outcome of the method of Group I, which is a polypeptide expressed in a cell.

Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the polypeptide such as claimed could be made by another process besides expression in a cell such as peptide synthesis.

Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product such

as claimed could be used in a materially different process of using that product such as for *in vitro* detection of a deficient BRDII-BFI gene.

Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product such as claimed could be used in a materially different process of using that product such as for screening compounds for detection of transcriptional regulation activity.

Inventions II and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product such as claimed could be used in a materially different process of using that product such as treating a subject.

Inventions III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product such as claimed could be used in a materially different process of using that product such as for *in vitro* detection of a deficient BRDII-BFI gene.

Inventions III and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product such as claimed could be used in a materially different process of using that product such as for screening compounds for detection of transcriptional regulation activity.

Inventions III and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product such as claimed could be used in a materially different process of using that product such as treating a subject.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura McGillem whose telephone number is (571) 272-8783. The examiner can normally be reached on M-F 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura McGillem, PhD
9/16/2005

DAVID GUZO
PRIMARY EXAMINER